INTERNATIONAL STANDARD

First edition 2015-10-01

Safety of toys —

Part 7:

Requirements and test methods for finger paints

Sécurité des jouets —

iTeh STPartie 7: Exigences et méthodes d'essai pour les peintures digitales (standards.iteh.ai)

ISO 8124-7:2015 https://standards.iteh.ai/catalog/standards/sist/7a6eccec-3893-4884-9360-2dedbd358d54/iso-8124-7-2015



Reference number ISO 8124-7:2015(E)

iTeh STANDARD PREVIEW (standards.iteh.ai)

<u>ISO 8124-7:2015</u> https://standards.iteh.ai/catalog/standards/sist/7a6eccec-3893-4884-9360-2dedbd358d54/iso-8124-7-2015



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ASO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 181, Safety of toys.

ISO 8124 consists of the following parts, under the general title *Safety of toys*:

- https://standards.iteh.ai/catalog/standards/sist/7a6eccec-3893-4884-9360-
- Part 1: Safety aspects related to mechanical and physical properties
- Part 2: Flammability
- Part 3: Migration of certain elements
- Part 4: Swings, slides and similar activity toys for indoor and outdoor family domestic use
- Part 5: Determination of total concentration of certain elements of toys
- Part 6: Certain phthalate esters in toys and children's products
- Part 7: Requirements and test methods for finger paints
- Part 8: Age determination guidelines

Introduction

This part of ISO 8124 contains requirements which are intended to reduce the risks to children when finger paints are used as intended or in a foreseeable way, bearing in mind the behaviour of children. In particular it is recognized that finger paints present different risks when compared to other toys because of their intended use which requires application to the hands and fingers of young children. It cannot be ruled out that some of the paint material will be ingested or flicked into the eye or that prolonged contact with the skin will occur. Therefore, in order to address the particular risks associated with finger paints, this part of ISO 8124 contains requirements relating to the ingredients that may be used in the manufacture of finger paints and limitations on certain impurities that may be found in these ingredients. It also sets out certain requirements on the packaging and labelling of finger paints.

Chemical Abstract Service Registry Numbers (CAS) or Colour Index Numbers given in the Tables are provided for information purposes only.

<u>Annex A</u> provides rationale for the requirements.

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Safety of toys —

Part 7: Requirements and test methods for finger paints

1 Scope

This part of ISO 8124 specifies requirements for the substances and materials used in finger paints. It is applicable to finger paints only.

It is not applicable to paints intended to be applied to the face or body e.g. face paints.

Additional requirements are specified for markings, labelling and containers.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. **RD PREVIEW**

ISO 787-9, General methods of test for pigments and extenders — Part 9: Determination of pH value of an aqueous suspension

ISO 8124-3:2010, Safety of toys — Part 3: Migration of certain elements

https://standards.iteh.ai/catalog/standards/sist/7a6eccec-3893-4884-9360-

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3 Terms and definitions

For the purposes of this document the following definitions apply.

3.1

finger paint

aqueous semi-solid or liquid, coloured mixture specially designed for children to apply directly to suitable surfaces with the fingers and hands

Note 1 to entry: Finger paint supplied in powder form is mixed with water according to the manufacturer's instructions before being considered in relation to this part of ISO 8124.

3.2

colourant pigment or dvestuff

Note 1 to entry: For definitions of pigment and dyestuff see <u>A.2</u>.

3.3

extender

material in granular or powder form, insoluble in the medium and used to modify or influence certain physical properties

Note 1 to entry: [SOURCE: ISO 4618:2014, definition 2.102, modified — Note 1 to entry deleted]

3.4

humectant

substance that delays the drying process

3.5

binding agent

water-soluble or miscible, non-volatile component that binds the paint to the surface to which it has been applied

3.6

preservative

substance that prevents the growth of undesirable micro-organisms

3.7

surfactant

surface active substance that reduces the surface tension of the solution

Note 1 to entry: It can be used to make components miscible.

3.8

embittering agent

substance that gives the product a bitter taste

4 Requirements

4.1 General

Finger paints supplied in powder form shall be assessed against this part of ISO 8124 when mixed with water in accordance with the manufacturer's instructions. **D**

When assessed according to the rules set out in the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), a finger paint shall not be classified with any of the following health hazards: ISO 8124-7:2015

- acute toxicity (hazard class 3:1), distributed and acut

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- skin corrosion/irritation (hazard class 3.2);
- serious eye damage/eye irritation (hazard class 3.3);
- respiratory or skin sensitization (hazard class 3.4);
- germ cell mutagenicity (hazard class 3.5);
- carcinogenicity (hazard class 3.6);
- reproductive toxicity adverse effects on sexual function and fertility or on development (hazard class 3.7);
- specific target organ toxicity single exposure effects other than narcotic effects (hazard class 3.8);
- specific target organ toxicity repeated exposure (hazard class 3.9);
- aspiration hazard (hazard class 3.10).

4.2 Colourants

See <u>A.2</u>.

4.2.1 Colourants used in finger paint shall not have any of the health hazard classifications set out in <u>4.1</u> (hazard class 3.1 to 3.10).

NOTE <u>Annex B</u> provides a list of commonly used colorants that have been found to meet the requirements of <u>4.2</u>, providing they meet the purity requirements specified. These fall into one or more of the following categories: Colourants permitted for use in food and/or cosmetics and other pigments which meet the general requirements of <u>4.1</u>.

4.2.2 Finger paints shall not contain azo colourants that by cleavage of one or more azo groups can produce the primary aromatic amines listed in <u>Tables 1</u> and <u>2</u> when tested in accordance with the test method specified in <u>Annex C</u>.

4.3 Preservatives

See <u>A.3</u>.

Finger paints shall be preserved using only the preservatives listed in <u>Annex D</u>. The maximum concentrations of preservatives shall not exceed the limits in column 4 of <u>Table D.1</u> in <u>Annex D</u>.

Methods for the determination of certain preservatives are set out in the EU Cosmetics Legislation, (see Bibliography) and should be used when evaluating the maximum concentrations specified in the column "maximum allowed concentration" of <u>Table D.1</u>. Alternative methods that provide an equivalent detection limit may also be used.

4.4 Migration of certain elements

See <u>A.4</u>.

The concentration of elements shall not exceed the maximum limit values for finger paint specified in ISO 8124-3:2010, Table 1. (standards.iteh.ai)

4.5 Limits for impurities

See <u>A.5</u>.

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4.5.1 Limits for primary aromatic amines

4.5.1.1 The primary aromatic amines listed in <u>Table 1</u> shall not be detectable when tested in accordance with the test method in <u>Annex C</u>.

Primary aromatic amines	CAS Number
Benzidine	92-87-5
2-Naphthylamine	91-59-8
4-Chloro-2-methylaniline (4-Chloro- <i>o</i> -toluidine)	95-69-2
4-Aminobiphenyl	92-67-1

Table 1 —	Primary	aromatic	amines
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4.5.1.2 Finger paint shall not contain carcinogenic primary aromatic amines (see <u>Table 2</u> for a non-exhaustive list of relevant substances) in a total amount exceeding 20 mg/kg, with no individual primary aromatic amine exceeding 10 mg/kg, when tested in accordance with <u>Annex C</u>. The limitation does not apply to aromatic aminocarboxylic acids or aminosulfonic acids.

Table 2 — Oth	er primary	aromatic amines	(non-exhaustive list)
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Primary aromatic amine	CAS Number		
o-Aminoazotoluene (4-o-Tolyazo-o-toluidine)	97-56-3		
^a For certain pigments limit values for 3,3'-Dichlorobenzidine are given <u>Annex B</u> , <u>Table B.1</u> .			

Primary aromatic amine	CAS Number
2-Amino-4-nitrotoluene (5-Nitro- <i>o</i> -toluidine)	99-55-8
4-Chloroaniline	106-47-8
2,4-Diaminoanisole	615-05-4
4,4'-Diaminodiphenylmethane (4,4'-Methylenedianiline)	101–77–9
3,3'-Dichlorobenzidine ^a	91-94-1
3,3'-Dimethoxybenzidine	119-90-4
3,3'-Dimethylbenzidine	119-93-7
3,3'-Dimethyl-4,4'-diaminodiphenylmethane (4,4'-Methylenedi-o-toluidine)	838-88-0
<i>p</i> -Cresidine (6-Methoxy-m-toluidine)	120-71-8
2, 2'- Dichloro-4, 4'- methylenedianiline (4,4'-Methylene-bis-2-chloroaniline)	101-14-4
4,4'-Oxydianiline	101-80-4
4,4'-Thiodianiline	139-65-1
<i>o</i> -Toluidine	95-53-4
2,4-Xylidine	95-68-1
2,6-Xylidine	87-62-7
4-Amino-3-fluorophenol ITeh STANDARD PREVIEW	399-95-1
6-Amino-2-ethoxynaphthalene (standards.iteh.ai)	not available
2-Methoxyaniline (<i>o</i> -Anisidine)	90-04-0
4-Aminoazobenzene ISO 8124-7:2015	60-09-3
4-Methyl- <i>m</i> -phenylenediamine (Toluene-2,4-clamine) standards/sist/7a6eccec-3893-4884-93	95-80-7
2,4,5-Trimethylaniline	137–17–7
Aniline	62-53-3
^a For certain pigments limit values for 3,3'-Dichlorobenzidine are given <u>Annex B</u> , <u>Table B.1</u> .	

Table 2 (continued)

4.5.2 Limits for other impurities

See <u>A.5</u>.

Finger paints shall not contain the impurities specified in <u>Table 3</u>, column 1 above the limits specified in column 2 when colourants specified in column 3 are used, when tested in accordance with <u>Annex E</u>.

Table 3 — Impurities in finger paints

Values in	milligrams	per	kilogram	of finger	paint
	0	L .	- 0 -	- 0-	T

Impurity	Limit	Finger paints of concern
Polychlorinated biphenyls	< 2	Finger paints containing chlorinated colourants or colourants manufac- tured in chlorinated solvents
Hexachlorobenzene (CAS No. 118–74–1)	< 5	Finger paints containing chlorinated colourants or colourants manufac- tured in chlorinated solvents
Benzo (α) pyrene (CAS No. 50–32–8)	< 0,05	Only for finger paints containing carbon black

4.6 Taste and smell

See <u>A.7</u>.

Finger paints shall not be sweetened, flavoured or fragranced.

An embittering agent in accordance with <u>Table 4</u> shall be added in order to discourage and minimize the ingestion of paint.

Embittering agent	CAS Number
Naringin	CAS 10236-47-2
Denatonium benzoate	CAS 3734-33-6

Table 4 — Embitte	ering agents
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The bitterness should be detectable by taste when the finger paint is diluted with water in a ratio of 1:100. The following levels have been found suitable: naringin 1 %; denatonium benzoate 0,0004 % (4 mg/kg). The relative bitterness of these substances is approximately 1:3 000 (naringin : denatonium benzoate).

The embittering agent and its concentration should be such that it provides a bitter taste during the expected lifetime of the finger paint.

4.7 pH value

See A.8.

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The pH value of the finger paint shall be between 4,0 and 10,0 when tested in accordance with ISO 787-9.

4.8 Binding agents, extenders, humectants and surfactants

Finger paints shall only use binding agents, 4×10^{-10} (hazards classified with any of the health hazards set out in in $\frac{4.1}{4.1}$ (hazards class 3.1 to 3.10).

NOTE See <u>Annex F</u> for a list of compounds known to be commonly used in finger paints.

4.9 N-Nitrosamines

See <u>A.9</u>.

Finger paints shall not contain more than 0,02 mg/kg of N-nitrosodiethanolamine (NDELA), CAS No.:1116-54-7.

NOTE One suitable and validated test method is detailed in EN 71–12:2013, 7.2.1 and Clause 8. Other test methods may be used provided they are validated for finger paints.

4.10 Container

See <u>A.10</u>.

Containers used for finger paints shall not have a design that is likely to be mistaken by children with containers of foodstuffs or drinks.

Manufacturers should take into consideration the material(s), shape, volume, colours, labelling, other packaging and the means of access to the contents, when assessing similarity with containers of foodstuff or drinks.

Annex A (informative)

Rationale

A.1 Finger paints

In addition to water, *finger paints* essentially consist of colourants, binders, preservatives and embittering agents and may additionally contain extenders, humectants and surfactants. *Finger paints* may be coloured by using colouring substances or mixtures containing colouring and other ingredients which are incorporated into a finger paint to impart colour to the finger paint.

A.2 Colourants

See <u>4.2</u>.

<u>Annex B</u> contains a list of colourants which are suitable for finger paints subject to them meeting certain purity requirements. It includes colourants specific to finger paints, food colourants and cosmetic colourants.

More detailed requirements on aromatic amines are included in order to exclude risks which may derive from impurities in colourants. (standards.iteh.ai)

Dyes are intensely coloured or fluorescent organic substances only, which impart colour to a substrate by selective absorption of light. They are soluble and/or go through an application process which, at least temporarily, destroys any crystal structure by absorption, solution, and mechanical retention, or by ionic or covalent chemical bonds.

Pigments are coloured, black, white or fluorescent particulate organic or inorganic solids which usually are insoluble in, and essentially physically and chemically unaffected by, the vehicle or substrate in which they are incorporated. They alter appearance by selective absorption and/or by scattering of light. Pigments are usually dispersed in vehicles or substrates for application, as for instance in the manufacture or inks, paints, plastics or other polymeric materials. Pigments retain a crystal or particulate structure throughout the coloration process.

A.3 Preservatives

See <u>4.3</u>.

The use of appropriate preservatives in water-based systems like finger paints is necessary in order to provide protection against the growth of bacteria, fungi and yeasts and maintain a hygienic compound.

Preservatives allowed for use in finger paints are listed in <u>Annex D</u>. The following properties were taken into consideration when drafting this list: high efficacy with respect to micro-organisms accompanied by suitable toxicological performance (e.g. low human toxicity, low volatility, low odour), suitable technical performance (e.g. solubility in water-based systems, stability against other ingredients, stability against chemical or physical influences) and suitable environmental performance [e.g. low adsorbable organic halogens (AOX), low persistence]. The list includes, for example, preservatives that are allowed for cosmetic use or for food use.

A.4 Elements

See <u>4.4</u>.

The limit values and test methods for the migration of certain elements in finger paints are specified in ISO 8124-3, Table 1, row 3.

A.5 Limits for primary aromatic amines

See <u>4.5.1.1</u> and <u>4.5.1.2</u>.

Table 1 lists the four primary aromatic amines which shall not be determinable in finger paints at the limit of quantification (LOQ) using the method described in <u>Annex C</u> using GC-MS as the detection technique. Table 2 lists 24 primary aromatic amines which were taken from Table 2 of EN 71-7:2014 entitled "Other carcinogenic primary aromatic amines (non-exhaustive list)". Therefore, the listing of primary aromatic amines in <u>Table 2</u> of this part of ISO 8124 has been described as a non-exhaustive list and does not preclude other primary aromatic amines from being analysed. The information provided in Chromatography (C.6.5) and Precision (C.8) includes the four primary aromatic amines listed in <u>Table 1</u>, and 18 primary aromatic amines from <u>Table 2</u>. The inclusion of 18 rather than all 23 primary aromatic amines in <u>Table 2</u> reflects the difficulty in obtaining the suitable commercial standards at the time of writing this part of ISO 8124. The information in C.5 and C.8 should provide the competent analyst with indicative information in the determination of other primary aromatic amines where/when calibration standards are available. The limitation for primary aromatic amines does not apply to aromatic aminocarboxylic acids or aminosulfonic acids because they are considered to be harmless.

A.6 Limit for benzo(α)pyrene

See <u>4.5.2</u>. **iTeh STANDARD PREVIEW**

Benzo(α)pyrene in finger paints is limited to the currently technically achievable analytical limit of quantitation (LOQ) of 0,02 mg/kg.

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A.7 Taste and sime Andards.iteh.ai/catalog/standards/sist/7a6eccec-3893-4884-9360-2dedbd358d54/iso-8124-7-2015

See <u>4.6</u>.

The addition of sweeteners, flavourings and fragrances to a finger paint may be determined by an assessment of the individual ingredients in the formulation of the finger paint.

The requirement to add an embittering agent to finger paints is intended to minimize potential oral ingestion by young children who may deliberately or accidentally put some of the finger paint in their mouth.

It should be noted that products with added embittering agents show remarkable bitterness, which may remain for a while after putting it into the mouth.

Experience has shown that the bitterness in finger paint will last for the product's lifetime, if one of the two embittering agents in <u>Table 4</u> is used in diluted finger paint as given in the Note in <u>4.6</u>.

A.8 pH value

See <u>4.7</u>.

The use of calcium carbonate may raise the pH value as a result of more dissociation by dilution with water in accordance with ISO 787-9 up to pH 10.

Some types of formulations containing calcium carbonate show pH values higher than 10 because the dilution of the finger paint is made with distilled water. This may also be found for small amounts of calcium carbonate in finger paint. Such a high increase as an analytical artefact does not happen when tap water is used to dilute the finger paint.

A.9 N-Nitrosamines

See <u>4.9</u>.

To avoid the possible formation of N-nitrosamines avoid using formulations that combine diethanolamine andtriethanolamine (which is known to be often contaminated with diethanolamine or which can be decomposed to diethanolamine) with possible sources of nitrite that may be present in certain preservatives (e.g. bronopol) and other raw materials.

Work undertaken during the development of EN 71-12:2013, showed that the only N-nitrosamine of relevance for finger paints is N-nitrosodiethanolamine (NDELA), CAS No.:1116-54-7. Consequently this part of ISO 8124 sets a limitation on NDELA only. EN 71-12:2013 mentions other N-nitrosamines because this aligns with the EU toy safety directive but other N-nitrosamines are not known to occur in finger paints.

EN 71-12:2013 contains a validated test method for the determinations of NDELA in finger paints but other test methods may be used provided they are validated for determination of NDELA in a typical finger paint matrix.

A.10 Containers

See <u>4.10</u>.

This requirement is intended to minimize the potential for a child to mistake finger paint for a foodstuff or a drink. The requirement is one of a series of precautionary measures (e.g. embittering agents, no flavour, no sweetening, no fragrance, warning to parents to supervise) intended to discourage the ingestion of finger paints by typical users (e.g. two years and above).

A.11 Labelling guidelines

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See <u>Annex G</u>.

Young children have a propensity for exploring objects orally. The warning phrase recognizes the fact that children under three years of age may be tempted to taste or eat the finger paint and this is something that the supervisor would be expected to discourage or prevent. Even though finger paints that are in conformity with this part of ISO 8124 may be considered to present a minimal risk, ingestion of repeated amounts of finger paint is not recommended.

Annex B (informative)

Non exhaustive list of colourants that are commonly used in finger paints and need to be in compliance with both the general and specific purity requirements

Table B.1 lists organic colourants commonly used in finger paints.

No.	Colour	CI Generic Name ^a	CI Constitution Number	CAS Number	Limitations, requirements and information
1	Yellow	Pigment Yellow 1	11680	2512-29-0	See ^b .
					Check purity criteria for amine limits and that excess coupling component ^d is less than 1 000 ppm (parts per million).
2		Pigment Yellow 3	11710	6486-23-3	See ^b .
		iTeh STA	NDARD	PREVIE	Check purity criteria for amine limits and that excess coupling component ^d is less than 1 000 ppm.
3		Pigment Yellow 12 (sta	²¹⁰⁹ ards.i	6358-85-6	3,3'-Dichlorobenzidine \leq 5 mg/kg: see <u>C.1</u> detection limit of the method.
4		Pigment Yellow 13	21100 <u>ISO 8124-7:20</u>	5102-83-0 <u>15</u>	3,3'-Dichlorobenzidine \leq 5 mg/kg: see <u>C.1</u> detection limit of the method.
5		Pightent/senedards.iteh.ai/ca 2dec	t <mark>e109/s</mark> tandards/sis bd358d54/iso-812	1 5468<u>07507</u>3893-488 14-7-2015	$3,3^{2}$ Dichlorobenzidine $\leq 5 \text{ mg/kg: see } \frac{C.1}{C.1}$ detection limit of the method.
6		Pigment Yellow 17	21105	4531-49-1	3,3'-Dichlorobenzidine \leq 5 mg/kg: see C.1 detection limit of the method.
7		Pigment Yellow 74	11741	6358-31-2	Check purity criteria for amine limits and that excess coupling component ^d is less than 1 000 ppm.
8		Pigment Yellow 138	56300	30125-47-4	
9		Pigment Yellow 139	56298	36888-99-0	
10		Pigment Yellow 151	13980	31837-42-0	
11	Yellow	Pigment Yellow 154	11781	68134-22-5	Check purity criteria for amine limits and that excess coupling component ^d is less than 1 000 ppm.
12		Pigment Yellow 155	200310	68516-73-4	
13		Pigment Yellow 185	56290	76199-85-4	
14		Natural Yellow 3	75300	458-37-7	Food grade, for example see current European legislation (2008/128/EC), E 100
15		Natural Yellow 6	75100	8 9 3 8 2 - 8 8 - 7 27876-94-4	

Table B.1 — Organic colourants which are commonly used in finger paints

^a The Colour Index is published by The Society of Dyers and Colourists, PO Box 244, Perkin House 82 Grattan Road, Bradford, West Yorkshire BD1 2JB, United Kingdom, <u>www.colour-index.org</u>. Colourants are classified using both their CI generic name and their constitution number. These relate only to the "essential colourant" as defined by the Colour Index.

^b This substance is restricted in Regulation (EC) No 1223/2009^[8] as follows: "Not to be used in eye products" or "Not to be used in products applied on mucous membranes", as applicable.

c This substance is restricted in Regulation (EC) No 1223/2009^[8] as follows: "Rinse-off products".

d Azo colourants are typically formed by a reaction sequence of diazotization of a primary aromatic amine which is referred to as the diazo component, followed by reaction (known as "coupling") with a compound having active methylene groups referred to as a coupling component.